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EXHIBIT C

Endoscopy Division
Smith & Nephew, Inc.
150 Minuteman Road, Andover, MA 01810 U.S.A.
Telephone: (978) 749-1000
Fax: (978) 749-1443

Smith+Nephew

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

BioRCI® Screw Modification
Date Prepared: 18 July 2003

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road
Andover, MA 01810

B. Company Contact

Marion W. Gordon, RAC
Regulatory Affairs Specialist
Phone: 978-749-1371 Fax: 978-749-1443

C. Device Name

Trade Name:	BioRCI® Screw
Common Name:	Bone fixation screw
Classification Name:	Smooth or metallic bone fixation fastener per 21 CFR § 888.3040

D. Predicate Devices

The Smith & Nephew Modified BioRCI® Screw is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device(s) in commercial distribution: BioRCI® Screw, K992396.

E. Description of Device

The Modified BioRCI® Screw is an interference screw in the range of 7-12mm in diameter and 20-35mm in length.

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F. **Intended Use**
The BioRCI® Screw is used for fixation of bone-tendon-bone or soft tissue grafts during Anterior/Posterior Cruciate Ligament (ACL/PCL) reconstruction procedures.

G. **Comparison of Technological Characteristics**
The Modified BioRCI® Screw incorporates a substantially equivalent design, using the same material, manufacturing, fundamental scientific technology, packaging, labeling, sterilization, and intended use as those featured in the currently commercialized BioRCI® Screw line.

H. **Summary Performance Data**
In vitro performance testing, material biocompatibility and sterilization validation demonstrate the modified device is safe, substantially equivalent and performs as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2003

Ms. Marion W. Gordon, RAC
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Endoscopy Division
150 Minuteman Road
Andover, MA 01810

Re: K032224
Trade/Device Name: BioRCI® Screw Modification
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: July 18, 2003
Received: July 21, 2003

Dear Ms. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus. permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K032224

Device Name: BioRCI® Screw Modification

Indications For Use:
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Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032224

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes OR Over-The-Counter Use No
(Per 21 CFR 801.109)